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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

PATRICK FRATELLONE, M.D., d/b/a
FRATELLONE MEDICAL ASSOCIATES, LLP,

Plaintiff,

- against -

KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services,

Defendant.

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08 Civ. 3100 (RMB) (RLE)

ORDER

I. Background

On December 3, 2008, Patrick Fratellone, M.D., a cardiologist, d/b/a Fratellone Medical Associates, LLP ("Plaintiff" or "Fratellone"), filed an amended complaint ("Amended Complaint") pursuant to 42 C.F.R. § 405.857, seeking judicial review of a final decision rendered on February 21, 2008 by Michael O. Leavitt, then-Secretary of the Department of Health & Human Services ("Defendant" or "Secretary") which upheld a determination by the Medicare Appeals Council ("MAC") that Fratellone had been reimbursed improperly by Medicare for specific medical services that he provided to eight beneficiary patients. (See Am. Compl. ¶ 22); see also 42 U.S.C. §§ 1395 et seq.; 42 C.F.R. §§ 405.904(a)(2), 405.1136.

Secretary of the Department of Health & Human Services Kathleen Sebelius is automatically substituted as a defendant for former Secretary Michael O. Leavitt. <u>See</u> Fed. R. Civ. P. 25(d). Additionally, The Centers for Medicare and Medicaid Services was improperly named as a defendant. See 42 C.F.R. § 405.1136(d).

Plaintiff's Amended Complaint also seeks judicial review of the Medicare reimbursement decision as it relates to three additional beneficiaries. (See Am. Compl. ¶ 6; see also infra Part III.1.)

Plaintiff had treated these patients, each of whom suffered from angina (chest pains), using a method known as Enhanced External Counterpulsation ("EECP" or "ECP"). (See

Administrative Record ("A.R.") at 00159-00163.) After initially reimbursing Plaintiff for these

EECP treatments, Empire Medicare Services ("Empire"), a Medicare contractor, determined that the treatments were not medically "reasonable and necessary" under the terms of Title 42 of the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), because the patients did not suffer from disabling angina. Empire demanded that Fratellone repay \$67,334.86, which represented the amount that Fratellone had been reimbursed by Empire for the eleven beneficiaries named in the Amended Complaint. (See supra note 1.).

On January 26, 2009, Defendant moved for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."), requesting that this Court affirm the Secretary's adoption of the MAC's final decision because, among other reasons, the MAC's "conclusion is supported by substantial evidence" that the services rendered by Fratellone were neither reasonable nor necessary because his patients did not suffer from disabling angina. (Def. Mem. at 1, 17; see A.R. at 00167 ("[T]he evidence submitted for all of the beneficiaries fails to establish that any of them suffered from disabling angina[.]").)

On March 12, 2009, Plaintiff filed an opposition and cross-motion for summary judgment pursuant to Fed. R. Civ. P. 56, arguing, among other things, that the MAC "incorrectly held that [Fratellone] was not entitled to payment and hence [that] Empire was entitled to recover the overpayment" because "each of these eleven (11) patients suffered from disabling angina and

Only Class III and Class IV angina, on a scale of I to IV, are considered to be "disabling." EECP is not approved for Class I or Class II angina. (Mem. of Law in Supp. of Def. Mot. to Dismiss, dated Jan. 26, 2009 ("Def. Mem."), at 4); see also Medicare National Coverage Determination Manual, Pub. 100-03, Ch. 1, Sec. 20-20.

had co-morbidities that permitted [Plaintiff] to treat them with EECP as opposed to invasive cardiac procedures such as surgery." (Mem. of Law in Opp'n to Def. Mot. to Dismiss & in Supp. of Pl. Mot. for Summ. J., Mar. 12, 2009 ("Pl. Mem."), at 1, 6.) Fratellone also argues that his opinion should have been accorded special weight during the administrative review process because he was the "treating physician" for the eleven patients in question. (Pl. Mem. at 4–5, 9–10; see also A.R. at 00168.)

Defendant filed a reply on April 2, 2009, (see Reply Mem. in Further Supp. of Def. Mot. to Dismiss Am. Compl. & in Opp'n to Pl. Cross-Mot., Apr. 2, 2009 ("Def. Reply")), and Plaintiff filed a sur-reply on April 16, 2009. (See Reply Mem. of Law in Further Opp'n to Def. Mot. to Dismiss & in Further Supp. of Pl. Mot. for Summ. J., Apr. 16, 2009 ("Pl. Reply").)

On August 7, 2009, United States Magistrate Judge Ronald L. Ellis, to whom the matter had been referred, issued a thorough Report and Recommendation ("Report"), recommending that the Secretary's motion for judgment on the pleadings be granted, and Fratellone's crossmotion for summary judgment be denied. Judge Ellis found, among other things, that: (1) "[t]he exhaustion requirement can be waived for futility" with respect to the three beneficiaries whose claims were not appealed to the MAC and Plaintiff's request for judicial review could "include his claims as to all eleven beneficiaries"; (2) the Secretary's "finding that the [EECP] treatment was not eligible for Medicare coverage . . . is supported by substantial evidence"; and (3) even assuming, arguendo, that the "treating physician rule" were applicable to Medicare cases, "Fratellone failed to submit well-documented evidence to support his medical conclusions [i.e.,

On March 12, 2009, Plaintiff filed an affidavit in support of his cross-motion. (Aff. of Patrick Fratellone, M.D., dated March 12, 2009 ("Fratellone Aff.").)

that the eleven patients suffered from disabling angina], and therefore, his medical opinion is not entitled to more evidentiary weight." (Report at 8–9, 14, 16, 17.)

The Report advised that, "[p]ursuant to Rule 72 [of the] Federal Rules of Civil Procedure, the parties shall have ten (10) days after being served with a copy of the recommended disposition to file written objections to this Report." (Report at 17.)

On August 27, 2009, Defendant filed objections to the Report ("Objections") arguing, among other things, that Judge Ellis erred in his "conclusion that the exhaustion requirement should be waived" as to three (additional) patients included in the Amended Complaint because "the mere fact that a plaintiff is not likely to receive the relief he seeks through the administrative process does not render exhaustion futile." (Objections at 3–4.) As of the date of this Order, Plaintiff has neither filed objections nor a response to Defendant's Objections.

For the reasons set forth below, the Report is adopted in its entirety.

II. Standard of Review

In its review of a magistrate judge's report and recommendation, a district court may adopt those sections that are not clearly erroneous and to which no objections have been made. Fed. R. Civ. P. 72(b); Thomas v. Arn, 474 U.S. 140, 149 (1985); DirecTV Latin America, L.L.C. v. Park 610, L.L.C., 614 F. Supp. 2d 446, 448 (S.D.N.Y. 2009). The court "shall make a de novo determination of those portions of the report or specified findings or recommendations to which an objection is made." 28 U.S.C. § 636(b)(1)(C); see also Donahue v. Global Home Loans & Fin., Inc., No. 05 Civ. 8362, 2007 WL 831816, at *1 (S.D.N.Y. Mar. 15, 2007). "A district judge may accept, set aside, or modify, in whole or in part, the findings and recommendations of

the Magistrate Judge as to such matters." <u>DirecTV</u>, 614 F. Supp. 2d at 448; <u>see also Knox v.</u>
Palestine Liberation Org., No. 03 Civ. 4466, 2009 WL 1765826, at *1 (S.D.N.Y. June 17, 2009).

III. Analysis

The facts and procedural history set forth in the Report are incorporated herein by reference. Having conducted a <u>de novo</u> review of the Report, Defendant's Objections, and the applicable legal authorities, the Court finds that the determinations and recommendations in the Report are supported by the record and the law in all respects. <u>See Pizarro v. Bartlett</u>, 776 F. Supp. 815, 817 (S.D.N.Y. 1991). Defendant's Objections do not provide any basis for departing from the Report's recommendations. As to any portion of the Report to which no objections have been made, the Court concludes that the Report is not clearly erroneous. <u>Id.</u> at 817.

(1) Exhaustion of Administrative Remedies

Judge Ellis properly concluded that the exhaustion requirement as to the three beneficiaries whose claims Plaintiff did not appeal to the MAC "can be waived for futility[.]" (Report at 8 (citing Pavano v. Shalala, 95 F.3d 147, 151 (2d Cir. 1996))); see also Pavano, 95 F.3d at 150 ("Plaintiff's failure to exhaust" administrative remedies can be excused if, among other reasons, "exhaustion would be futile."); Marcus v. Sullivan, 926 F.2d 604, 614 (7th Cir. 1991). Judge Ellis properly undertook a de novo review of the findings made by the administrative law judge as to the three cases and decided that "no different outcome would result had the MAC considered their files," because the records of these three beneficiaries "contain weaker evidence of the presence or diagnosis of disabling angina" than the files that the MAC did review. (Report at 9); see also Clark v. Astrue, No. 06 Civ. 15521, 2007 WL 737489, at *4 (S.D.N.Y. 2007).

(2) Substantial Evidence

Judge Ellis properly concluded that the Secretary's denial of Fratellone's appeal of the MAC's reimbursement decision was supported by substantial evidence in the administrative record. (See Report at 10); see also 42 U.S.C. § 1395ff(b)(1); N.Y. ex rel. Stein v. Sec'y of Health & Human Servs., 924 F.2d 431, 433 (2d Cir. 1991) ("[T]he proper standard of review is whether the Secretary's denial of reimbursement is supported by substantial evidence[.]"). Among other things, Judge Ellis found that "the evidence Fratellone cites in support of his position fails to satisfy the explicit requirements of the NCD" because neither Fratellone's contemporaneous medical records nor a series of letters that he subsequently prepared "include[d] an actual diagnosis of [disabling] angina[.]" (Report at 13, 14 (citing A.R. at 00166-00168)); see also Estate of Frohnhoefer v. Leavitt, No. 06 Civ. 1236, 2007 WL 841917, at *6 (E.D.N.Y. Mar. 19, 2007).

Judge Ellis also considered Fratellone's March 12, 2009 affidavit, even though it was not part of the administrative record below. (Report at 7 ("Because the question before this Court requires a review of the record as it was presented to the Secretary, and because Fratellone's affidavit does not introduce new and material evidence, the Court will consider it as an aid to understand and highlight Fratellone's position[.]").) The affidavit did little more than restate Fratellone's position that, among other things, the "beneficiaries suffered from disabling angina and that they were not readily amenable to surgical intervention because they had co-morbid states which created excessive risk[.]" (Fratellone Aff. ¶ 9.)

(3) Treating Physician

Judge Ellis properly concluded that, even assuming, arguendo, that the "treating physician rule" applies in the Medicare context, "the Secretary's decision should be upheld" because "Fratellone failed to submit well-documented evidence to support his medical conclusions, and therefore, his medical opinion is not entitled to more evidentiary weight." (Report at 16 (citing A.R. at 00004, 00168)); see Arruejo v. Thompson, No. 00 Civ. 2402, 2001 WL 1563699, at *14 (E.D.N.Y. July 3, 2001) ("[T]he opinion of a treating physician is entitled to special weight if it is 'well-supported by medically acceptable clinical and laboratory diagnostic techniques and . . . not inconsistent with the other substantial evidence in the record."") (quoting Standards for Consultative Examinations and Existing Medical Evidence, 56 Fed. Reg. 36,936 (Aug. 1, 1991)). Judge Ellis noted that "despite the fact that Fratellone was given the opportunity to provide additional evidence to the ALJ, 'the assertions of medical necessity contained in the summaries prepared by [Fratellone, for the ALJ] three years after the treatment dates were effectively at odds with the beneficiaries' more contemporaneous medical records.' [and] Fratellone failed to document [a Class III or IV angina] diagnosis as to these eleven beneficiaries." (Report at 16 (citing A.R. at 00004); see A.R. at 00168); see also Snell v. Apfel, 177 F.3d 128, 133 (2d Cir. 1999) ("When other substantial evidence in the record conflicts with the treating physician's opinion, however, that opinion will not be deemed controlling. And the less consistent that opinion is with the record as a whole, the less weight it will be given.").

IV. Conclusion & Order

For the reasons set forth in the Report and herein, the Court adopts Magistrate Judge

Ellis's Report in its entirety and grants Defendant's motion for judgment on the pleadings [#21]

and denies Plaintiff's cross-motion for summary judgment [#26]. The Clerk of Court is respectfully requested to enter judgment and close this case.

Dated: New York, New York September 16, 2009

RICHARD M. BERMAN, U.S.D.J.